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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,628	07/19/2001	Joanne Louise Whitaker	CM1993M	7144

27752      7590      12/28/2004

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EXAMINER

DOUYON, LORNA M

ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/889,628	<b>Applicant(s)</b> WHITAKER ET AL.	
<b>Examiner</b> Lorna M. Douyon	<b>Art Unit</b> 1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 15 October 2004.
- 2a)  This action is FINAL.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1, 16-19, 21-28 and 32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1, 16-19, 21-28 and 32 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

Art Unit: 1751

1. This action is responsive to the amendment filed on October 15, 2004.
2. The objection to the specification is withdrawn in view of Applicants' amendment.
3. The rejection of claim 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants' amendment.
4. The rejection of claims 1, 16-19, 25-28 and 32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,544,943; claim 6 of U.S. Patent No. 6,544,944; claim 8 of U.S. Patent No. 6,551,981; claim 3 of U.S. Patent No. 6,551,982; or claim 8 of U.S. Patent No. 6,589,932; each in view of Davidson (US Patent No. 3,951,821) is withdrawn in view of Applicants' amendment.
5. Claims 1, 16-19, 21-28 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,770,616 in view of Davidson.

US Patent No. 6,770,616 teaches a similar tablet having two phases wherein the first phase is formed by compression at a pressure greater than that of at least one second phase, the tablet comprising polymeric disintegrants and solubility aid comprising hydrated salts as those recited except for the particle size of the polymeric disintegrant as required in the present claims, the first phase having a mould and the child bite strength as that recited.

Art Unit: 1751

Davidson teaches disintegrating agents for tablets wherein the disintegrating agents include cellulose or cellulose acetate hollow fibers having inside diameters on the order of about 5 to about 1000 microns and a tubule length from about 50 microns to 2 to 3 millimeters, the tubules having outside diameters ranging from about 10 to about 50 microns to about 300 to about 1100 microns and axial length is preferably about 100-1000 microns (see abstract; col. 1, line 60 to col. 2, line 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect the polymeric disintegrants of US '616 to have a particle size within those recited because it is shown by Davidson that polymeric disintegrating agents for tablets have sizes which overlap those recited. With respect to the to the first phase having a mould, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the first phase with a mould because this is just a matter of obvious design choice. With respect to the child bite strength property of the tablet it would have been obvious to one of ordinary skill in the art at the time the invention was made to reasonably expect said property to be within those recited because similar tablets with similar ingredients have been utilized.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lorna M. Douyon whose telephone number is (571) 272-1313. The examiner can normally be reached on Mondays-Fridays from 8:00AM to 4:30 PM.

Art Unit: 1751

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Lorna M. Douyon*

Lorna M. Douyon  
Primary Examiner  
Art Unit 1751